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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,872	03/16/2001	Peter Zhu	JOHNA.058A	7471
27777	7590	07/30/2004	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			CROSS, LATOYA I	
			ART UNIT	PAPER NUMBER
			1743	
DATE MAILED: 07/30/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/810,872	Applicant(s) ZHU ET AL	
	Examiner LaToya I. Cross	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10-23 and 25-33 is/are pending in the application.
- 4a) Of the above claim(s) 15-23, 25-29 and 31 is/are withdrawn from consideration.
- 5) ☒ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-14, 30, 32 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### DETAILED ACTION

This Office Action is in response to Applicants' remarks filed on May 26, 2004. Claims 1-7, 10-23 and 25-33 are pending. Claims 15-23, 25-29 and 31 are withdrawn from consideration.

#### *Claim Observations*

Claim 1 state that the second reaction step produces a first color. Claim 10 states that first reaction produces a second color. The phrase is unclear because Applicants refer to a first color in the context of the second reaction (claim 1), and a second color in the context of the first reaction (claim 10). It would be clearer if the first color denotes the produce of the first reaction and the second color denotes the produce of the second reaction.

#### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-7, 10-12, 14 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,471,055 to Opp.

Opp teaches a process for determining whether the concentration of aldehyde in a sample is in excess of a predetermined concentration. The predetermined concentration of aldehyde is the point of interest of aldehyde. The method for determining whether aldehyde is present in a predetermined concentration taught by Opp comprises mixing the test sample with

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a first reaction system which reacts with carbonyl group in aldehydes, followed by reaction of the resultant product with a second reaction system, which reacts with any unreacted aldehyde, and detecting any visual formation of a second reaction product, as recited in claim 1 (col. 14, lines 7-41). With respect to Applicants' claimed limitation of the first reaction step occurring in the presence of the second reactant, Opp teaches at col. 3, lines 17-24 that the two reaction systems can be combined simultaneously with the sample at the beginning of the assay. The aldehydes to be tested are those used in disinfecting systems (in germicidal capacities) having at least one  $-CHO$  moiety, which includes glutaraldehyde, as recited in claims 6 and 7. The first reaction system includes reactants which form a colorless derivative of aldehyde, such as hydroxylamine or hydrazine, as recited in claim 5 (col. 4, lines 15-30). The second reaction system includes reactants that form aldehyde derivatives which are visually distinguishable from the first reaction products, such as amino acids, including glycine and lysine, as recited in claims 2-4 (col. 4, lines 38-55). Opp teaches that the first reaction products are colorless, as recited in claim 10 (col. 4, lines 15-17, col. 14, lines 42-43). With respect to claim 11, Opp teaches that the amount of first reaction system completely transform the amount of aldehyde equal to the predetermined amount, while the second reaction system provides a visual color where the amount of aldehyde exceeds the predetermined amount. Where the amount of aldehyde is less than the predetermined amount (1% for disinfecting processes), it would be inherent that no color would form since there would not be an excess amount of aldehyde to react in the second reaction system. With respect to claim 12, each of examples I-IX of Opp teaches providing a fixed volume of sample (0.1-1 milliliter) to which the reactants are added. Further, with respect to claim 14, Opp teaches that the fixed volume of test sample is added to a

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7 cc reaction container (measuring device), where the reaction container contains the first reaction system reagents (hydroxylamine or hydrazine).

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(b) in view of the teachings of Opp '055.

***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Opp in view of US Patent 4,703,763 to McAlister et al.

The disclosure of Opp is described above. Opp fails to teach loading a fixed volume of test sample into a measuring device having a liquid impermeable membrane.

McAlister et al teach a device for sample a pre-set volume of test sample. The device is a syringe-type measuring device having a plug element (filter) arranged to be air-permeable, but liquid impermeable. This allows enough fluid sample to be up taken into the syringe and then allow the fluid flow to stop when the predetermined amount is taken in. See col. 1, lines 41-59. It would have been obvious to one of ordinary skill in the art to use the device of McAlister et al to measuring an exact amount of test sample in carrying out the method of Opp. Such will prevent using excess sample. Since it is important that the amount of reagents in the method of Opp be exact for the amount of sample, using the device of McAlister et al will alleviate false positives due to incorrect reagent to sample ratios.

Therefore, for the reason set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Opp and McAlister et al.

5. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Witonsky in view of Wu.

Witonsky et al teach a method for determining whether the concentration of disinfectant/sterilant exceeds a predetermined value. The method tests for sufficient glutaraldehyde amounts in a disinfecting solution using test strips (CIDEX OPA tests for phthalaldehydye). The method involves contacting a test sample with a test strip impregnated with a sulfite compound and an amino acid compound. The sulfite compound is sodium sulfite (col. 2, line 24). The amino acid is glycine (col. 2, line 27). The method by which excess glutaraldehyde is to be determined is explained in Wu. Glutaraldehyde reacts with sulfite to form a sulfite addition product, which reacts with glycine to form sodium glycinate. Excess glutaraldehyde reacts with sodium glycinate to form a colored product. Thus, the sulfite serves as a first reactant to react with the carbonyl group in the aldehyde and sodium glycinate serves as the second reactant to react with remaining aldehyde in the sample that is unreacted. See col. 2, lines 39-52 of Wu.

Witonsky et al teaches using sodium sulfite, but fail to teach using sodium bisulfite. Wu teaches that both sodium sulfite and sodium bisulfite are effective in processes for determining the presence of aldehydes (col. 1, line 65 – col. 2, line 12). It would have been obvious to one of ordinary skill in the art to substitute sodium sulfite in Witonsky et al for sodium bisulfite, since

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both are known in the art to be suitable in determining the presence of aldehydes. See MPEP 2144.06.

With respect to claim 33, where Applicants recite that the first reaction step is kinetically and thermodynamically favored over the first second reaction step, such would have been obvious to the ordinarily skilled artisan because Wu teaches that aldehyde in the sample reacts with the sulfite first prior to reacting with glycine. Thus, the first reaction step would obviously have to be favored over the second reaction step.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Witonsky et al and Wu.

### *Response to Arguments*

6. Applicant's arguments filed December 1, 2003 have been fully considered but they are not persuasive. With respect to the anticipatory rejection over Opp, Applicants argue that Opp fails to anticipate the claimed invention or make the claimed invention obvious because allegedly Opp does is not enabling for the first reaction to occur in the presence of the second reaction, as recited in instant claims 1 and 30.

In response, Applicants failed to state any reasons to support the statement that Opp is not enabling. It is the position of the Examiner that Opp is indeed enabling. Opp teaches at col. 3, lines 19-24, "If the reaction kinetics of the two reaction systems are such that the first reaction system acts first and goes to completion before the second reaction system has acted to any significant extent, the two reaction systems may be combined simultaneously with the sample at the beginning of the assay." Further, in claim 1 of the Opp patent at column 14, Opp teaches that that two reaction systems are "combined as a mixture". While Opp may not spell

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out how to determine if the reaction kinetics of the two reactions systems are such that the first reaction would go to completion before the second reaction, such is unnecessary. One of ordinary skill in the art would have been able to determine the reaction rates of both systems to determine whether the first reaction would proceed faster than the second reaction. Reaction rate formulas and other means are commonly used to determine reaction rates in reaction systems. Opp teaches that if the first reaction system would react with the aldehyde before the second reaction system reacts with the aldehyde, then both reaction systems could be added to the sample together. Thus, Opp does provide an enabling disclosure.

With respect to the rejection over Opp in view of McAlister, Applicants argue that there is no suggestion for using the combination. As stated in the rejection, the device of McAlister allows the user to take up a set amount of sample, preventing any waste and preventing the possibility of false positives due to the use of incorrect amounts of reagents. The ordinarily skilled artisan would have recognized that syringes are not only used in drawing blood; they are in fact used in a variety of capacities including in assaying.

With respect to the rejection over Witonsky in view of Wu, Applicants argue that Wu teaches that the sodium glycinate is a product of the first reaction (glutaldehyde reacting with sodium sulfite) and thus, sodium glycinate is not present during the first reaction. In response, Witonsky teaches that both sodium sulfite and glycine are impregnated in the indicator. When added to a sample containing glutaldehyde, the indicator produces a color change depending on the ratio of sulfite to glycine, which determine how sensitive the indicator is to glutaldehyde. Applicants are seemingly attempting to argue the intermediate reactions that take place leading up to the resulting color, denoting the presence of aldehyde. In Applicants example I, sodium bisulfite, glycine and aldehyde (OPA) are added together in the same manner that Witonsky

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teaches adding sodium sulfite, glycine and aldehyde together. The presence of an intermediate reaction product (sodium glycinate) does not negate the idea that Witonsky teaches the same reagents (with the exception of using sulfite instead of bisulfite) to determine aldehyde as Applicants claim.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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